DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 28, 2015

BIOSAF IN S.R.L.
C/O Mr. Maurizio Pantaleoni
C.E.O.
ISEMED S.R.L.
Via A. Altobelli Bonetti, 3/A
Imola, BO 40026
ITALY

Re: K133733
Trade/Device Name: WINSIX Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous dental implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: December 23, 2014
Received: December 29, 2014

Dear Mr. Pantaleoni:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin I. Keith, M.S
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K133733

Device Name
WINSIX IMPLANT SYSTEM

Indications for Use *(Describe)*
WINSIX Implant System is indicated for single or multiple tooth replacement, or for use in terminal intermediate edentulous sites in the mandible and/or the maxilla, and for totally edentulous arches. The system is designed to be surgically inserted in the bone structure of the mouth in order to replace missing teeth. It is intended for immediate loading when good primary stability is achieved and with appropriate occlusal loading.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary for the WINSIX Implant System

This 510(k) Summary is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92.

1. General Information

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Summary Preparation Date: *December 22, 2014*

2. Names

Device Name: WINSIX Implant System
Classification Name: Implant, Endosseous, Root-form / Endosseous dental implant abutment
Product Code: DZE / NHA
Regulation number: 872.3640/872.3630

3. Predicate Devices

The WINSIX Implant Systems is substantially equivalent to the following devices:

Applicant	Device name	510(k) Number
BT Lock	BT Lock Implant System	K073458
AstraTech	Microtherad Osseosped	K053384
Nobel Biocare	Nobel Speedy Implants	K050406
Implant Innovation	3i Osseotite Dental Implants	K063286
Implant Innovation	3i Osseotite Certain Dental Implants	K063341
Straumann USA	ITI Dental Implant System (Strauman Plus Implant)	K033922

For the endosseous dental implant Abutments the predicate devices considered are:

Applicant	Device name	510(k) Number
BT Lock	BT Lock Implant System	K073458
Straumann USA	Straumann RN synOcta	K073628
Nobel Biocare	Multi Unit Abutment for Astratech, Camlog and Ankilos Implant System	K061477

4. Device Description

The family of WINSIX Implant System is intended for the treatment of oral endosteal implantation in the upper and lower jaw and for the functional and esthetic oral rehabilitation of edentulous and partially dentate patients. The family of WINSIX Implant Systems can also be used for immediate or early load implantation following extraction or loss of natural teeth. Implants can be placed with immediate function on single tooth and/or appropriate occlusal loading to restore chewing function. The prosthetic restorations used are single crowns, bridges and partial or full dentures, which are connected to the implants by the corresponding elements (abutments).
The family of WINSIX Implant System includes the following devices:

- Fixtures
- Abutments

The fixtures are the endosseous dental implants. They implantable devices produced in commercially pure titanium (grade 4) , available in following models:

- K Model
- KT Model
- Conical Model
- TTi Model

with various diameters and lengths in order to meet diverse anatomical requirements. They are single use devices, supplied sterile and cannot be re-sterilised

Fixtures technical features and available length are summarized in the table below:

	K	KT	Conical	TTi
Shape:				
Body	Cylindrical Screw	Cylindrical Screw	Conical screws	Cylindrical Tapered thread
Neck	Straight with micro thread (Submersed)	Conical Without Microthread (Transmucosal)	Straight Without Microthread (Submersed)	Conical Without Microthread (Submersed)
Surface:				
Body	A) MRS: Sandblasted and etched B) FCC: electrochemical roughening with Titanium oxide			
Neck	Smooth	Smooth	Smooth	Smooth

	K	KT	Conical	TTi
Dimensions:				
Endosseus Diameter (mm)	3,3 – 3,8 – 4,5 – 5,2	3,3 – 3,8 – 4,5 – 5,2 – 5,9	3,3 – 3,8 – 4,5 – 5,2	3,8 – 4,5 – 5,2
Length of submerged part (mm)	9 – 11 – 13 – 15	7 – 9 – 11 – 13 – 15	9 – 11 – 13 – 15	9 – 11 – 13 – 15
Diameter / Length combination	Each Length is available for each diameter	Each Length is available for each diameter except: L:15 mm –D: 5,9 mm	Each Length is available for each diameter	Each Length is available for each diameter
Connection:				
Shape	Internal hexagon Free lock Key 2,3mm	Internal hexagon Free lock Key 2,3mm	Internal hexagon Free lock Key 2,3mm	Internal hexagon Free lock Key 2,3mm

The abutments give at the physician a complete prosthetic solutions in order to use the WINSIX implant system as intended. They have been divided in followings main groups:

- COVER SCREWS are used for the restorative phase after implantation
- HEALING SREWS are used to cover the fixtures and to model the mucosa during her healing
- ABUTMENTS are used for creation of screwed temporary or fixed elements. They have different features to allow the physician to adapt to the different anatomical situation. In detail:
    - The straight abutments are used for the construction of the fixed prosthesis when the implant axis are parallel in relation to the prosthetic axis
    - The angulated abutments with an angulation of 15°,17°,20°,25° and 30° are used for the creation of fixed or screwed prostheses in the case of disparallelism between implant axis and prosthetic axis.
    - The millable abutments can be personalised thanks to the precision of the industrially manufactured connection and the possibility to shape of the abutment through hand milling.
    - The flat shift abutments are used to create a screw retained prosthesis, to increase the gingival height, in case of soft tissue thickness over 2 mm. In this case, the Flat shift abutment could be fixed to the fixture and then the flat shift cylindrical direct abutment can be fixed over the flat shift abutment. The flat shift retentive direct flared abutment is used for impression taking. The Flat shift abutments can be used only with internal hexagon fixtures

According to the results of fatigue testing maximum recommended abutment angulation is 30°

5. Indications for Use

WINSIX Implant System is indicated for single or multiple tooth replacement, or for use in terminal intermediate edentulous sites in the mandible and/or the maxilla, and for totally edentulous arches.

The system is designed to be surgically inserted in the bone structure of the mouth in order to replace missing teeth. It is intended for immediate loading when good primary stability is achieved and with appropriate occlusal loading

6. Performance Data

Dimensions, materials and surface treatments are substantially equivalent to those of predicate devices. The following tests were performed on WINSIX implant system:

BIOCOMPATIBILITY

- Citotoxicity
- Intracutaneous reactivity

These tests were performed on abutments to evaluate the impact of the process of coloration.

The results of the reports listed above show that the WINSIX abutments are:

- Not Cytotoxic
- Satisfying the requirements for intracutaneous reactivity test

SURFACE VALIDATION TESTS

Surface treatment is performed on implants through a MRS -Micro Rough Surface (sandblasted and acid-etched) treatment or with FCC – Full Contact Covering (superficial chemical treatment) treatment. A specific study has been done on each surface treatment, as summarized below:

MRS – The following assays were performed:

- XPS analyses providing the qualitative and quantitative composition of the Micro Rough Surface coming in contact with the bone tissue
- SEM analyses providing either qualitative chemical information of the implant's Micro Rough surface or the evidence of the effectiveness of metallic material decontamination protocol.
- Cytotoxicity test on human osteoblastic cells (Saos-2) in contact with WINSIX implant with MRS.

The results demonstrate that the chemical composition of the micro-rough surface is exactly the same as the predicate device. The SEM analyses guarantee the total absence of accumulations, residuals and stains. The cytotoxicity test points out that the Micro-rough surface is not cytotoxic. Overall, such results demonstrate equivalent performance and chemical characteristics as the predicate devices.

FCC – The following assays were performed:

- XPS analyses providing the qualitative and quantitative composition of the Full Contact Covering surface.
- SEM analyses providing either qualitative chemical information of the FCC surface or the evidence of the effectiveness of metallic material decontamination protocol.
- Cytotoxicity test on mouse connective tissue fibroblasts (L-929) in contact with the FCC treated fixtures of the WINSIX implants.

The results demonstrate that FCC surfaces have the typical composition of the Ti and thus they may be found substantial equivalent to the predicate device. The SEM analyses guarantee the total absence of accumulations, residuals and stains. Finally the cytotoxicity test points out that the FCC surfaces are not cytotoxic. Overall, such results support technical and performance features of the FCC WINSIX Implants.

MECHANICAL TESTS

The Mechanical test were performed in compliance with "Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments" and "ISO 14801: 2007 - Dynamic fatigue test for endosseous dental implants" and demonstrated that the worst case chosen is able to resist to 5.000.000 cycles.

STERILIZATION AND PACKAGING SHELF LIFE

WINSIX implant system are sterilized with gamma ray sterilization to assure a SAL level of 10^{-6}
Shelf life granted is 5 years

7. Applicable Standards:

The Family of WINSIX Implant Systems have been developed and tested according to the following international standards:

ASTM F67 - Standard Specification for Unalloyed Titanium, for Surgical Implant Applications
ASTMF136 - Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI Alloy for Surgical Implant Applications
ISO 14801: 2007 - Dynamic fatigue test for endosseous dental implants
ISO 11137-1 Sterilization of health care products -- Radiation -- Part 1: Requirements for development, validation and routine control of a sterilization process for medical device
ASTM 1980 "Standard Guide For Accelerated Aging of Sterile Medical Devices Packages".
ISO 10993-5 Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity.
ISO 10993-10 - Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

8. Conclusions

Based on technological characteristics (intended use, material used, dimensions and features) and performance data (mechanical tests, biocompatibility tests, sterilization and shelf life) WINSIX implant system are substantially equivalent and perform as well than the identified predicate devices